

FILED

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
FT. MYERS DIVISION

CLERK, U.S. DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FT. MYERS, FLORIDA

DR. AND MRS. ROBERT SHARKEY
on behalf of RYAN REID SHARKEY,
a minor,

Plaintiffs,

v.

2:04-cv-552-FTM-29-SAC

Civil Action No.

FOOD AND DRUG ADMINISTRATION,
5600 Fishers Lane
Rockville, Maryland 20857

Defendant.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF
(INJUNCTIVE RELIEF SOUGHT)

1. Plaintiff brings this action under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, as amended.
2. This Court has both subject matter jurisdiction over this action and personal jurisdiction over the parties pursuant to 5 U.S.C. § 552(a)(4)(B). This Court also has jurisdiction over this action pursuant to 28 U.S.C. § 1331. Venue lies in this district under 5 U.S.C. § 552(a)(4)(B).
3. Ryan Reid Sharkey ("Ryan") is a child that was diagnosed by his treating physicians as having suffered severe injury from an adverse reaction to the hepatitis B vaccine.
4. Plaintiffs requested records from defendant to assist Ryan's physicians in determining whether an adverse reaction to the hepatitis B vaccine was in fact the cause of Ryan's severe injuries.

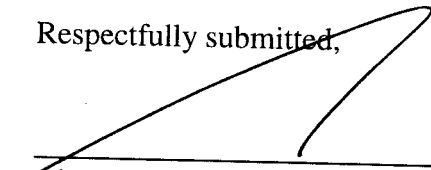
5. Furthermore, on Ryan's behalf, plaintiffs are petitioners in a federal compensation program for adverse reactions to vaccinations and require the above records to help prove that Ryan's injuries were caused by the hepatitis B vaccine.
6. Prompt release of the requested information is essential for the plaintiffs to be able to prove that Ryan's injuries were caused by an adverse reaction to the hepatitis B vaccine.
7. Plaintiffs are residents of Lee County, Florida and resided in Lee County, Florida at all time relevant hereto.
8. Defendant FOOD AND DRUG ADMINISTRATION is an agency of the United States within the meaning of 5 U.S.C. § 552(f), and has indicated that it has possession of and control over the records that plaintiffs seek.
9. Plaintiffs seek the Court to compel defendant to produce records reflecting the net number of doses in each lot of Recombivax HB and Engerix-B hepatitis B vaccine distributed in the United States.
10. By facsimile received by defendant on March 10, 2003 with the original sent by United States Certified Mail, plaintiffs requested copies of the above records.
11. Plaintiffs received no response to the request of March 10, 2003 from the defendant within the time allotted by law.
12. As plaintiffs had received no response to their request, in faxed letters of December 2, 2003, December 24, 2003, and December 30, 2003, plaintiffs' followed-up on their request of March 10, 2003.

13. In a letter of May 13, 2004, the Food and Drug Administration forwarded a letter stating that a search of the records of a subdivision of defendant did not reveal any records responsive to the request.
14. In a letter of June 22, 2004, defendant denied the request claiming that the plaintiffs' request sought "trade secret and confidential commercial information."
15. On April 4, 2004 plaintiffs administratively appealed by facsimile and United States certified mail the actual and constructive denials of their request.
16. In a letter of August 3, 2004, receipt of the administrative appeal by the appropriate agency was acknowledged.
17. More than 20 working days have passed, no response to the plaintiffs' administrative appeal has been received, and to date there has been no indication when a substantive response to the appeal can be anticipated.
18. Plaintiffs have a statutory right to the records they seek and there is no legal basis for defendant's refusal to disclose the records.

WHEREFORE, plaintiffs pray that this Court:

- A. Declare that defendant's withholding of the requested records is unlawful;
- B. Order defendant to make the requested records available to the plaintiffs as requested;
- C. Award plaintiffs their costs and reasonable attorneys' fees pursuant to 5 U.S.C. § 552(a)(4)(e); and
- D. Grant all other appropriate relief.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Altom M. Maglio', is written over a horizontal line.

Altom M. Maglio, Trial Counsel

Bar Number 88005

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Dated November 8, 2004